GENE LAB
SL6040A
User’s Manual

BIOER TENOLOGY CO.,LTD

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Thank you for choosing our products!
Please read user's manual carefully, before you use the lab at the first time!

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Important note

1. CONVENTION

Note: Please pay close attention to the important information in this column. Failure to follow the advice in this column will possibly result in damage to or the malfunctioning of the equipments.

Warring! This symbol reminds user should be cautious when performing this operation/procedure. Failure to follow the requirements in this column could possibly result in personal injury.

2. SAFETY

During the operation, maintenance, or repair of Gene Lab, the following safety measures should be taken. Otherwise, the safeguards provided by this lab are likely to be damaged, the rated safety level to be reduced, and the rated operation conditions to be affected.

Bioer Co. shall not be in any way responsible for the consequences resulting from operator's not observing the following requirements.

a) Grounding

A.C. power's grounding should be reliable to safeguard against an electric shock. The 4mm² hard wires are used in the lab's general electric source, and the general wire should be educed from the power supplier of the building to ceramic tie-in in the lab.

b) A.C. Power Considerations

Always make sure that the main voltage conforms to the required voltage and the main rated power no less than the required power (5000W), before the power is connected.

3. MAINTENANCE

Please refer to the Annex for the maintenance of the lab.

Warring! During the cleanout of operation desk, power socket, fans and lamps, power should be cut off.
It's forbidden to drop abluent into operation desk and the holes of power socket.
It's forbidden to wash operation desk and wall with caustic abluent.

Appendix: Cleaning Procedure for Gene Lab

1.PURPOSE:

In order to guarantee neatness of lab's surroundings and prevent contamination.

2.APPLICATION SCOPE:

Be suitable for cleaning and disinfection work to the lab's working surroundings, experimental tables, work clothes, pipettors, etc.

3.RESPONSIBILITY：

All staff in the lab should know very well and observe this procedure; the clearing work can be carried out by assigned personnel.

4.MODIFICATION ON THE PROCEDURE：

Any staff who use this procedure can bring forward the modification of the procedure. Before bring it into effect, the modification should be proved for its rationality, and authorized by branch director.

5.WORKING PROCEDURE：

5.1 Cleaning and disinfection tools suitable for each experimental area are all special, but cannot be misused.

5.2 Finishing experiment, please use 4% "84" disinfectant liquid or 10% sodium hypochlorite disinfectant liquid to clean the experimental tables, and use ultraviolet lamp to do disinfection.

5.3 In case samples or reagents overflow, please use 10% sodium hypochlorite to clean, scour with the clear water, and make relative records.

5.4 Please hand the work clothes to the laundry room for cleaning and disinfection every week. Pay close attention that work clothes in different areas cannot be washed in the same day.

5.5 Please clean pipettors with 10% sodium hypochlorite after daily use, and carry on the

high-pressured disinfection every two weeks.

5.6 Before the daily work is over, please turn on ultraviolet lamp to do ultraviolet disinfection for 60 minutes in the lab.

5.7 Please clean the instruments and equipments every day.

NOTE: This procedure is for reference only.

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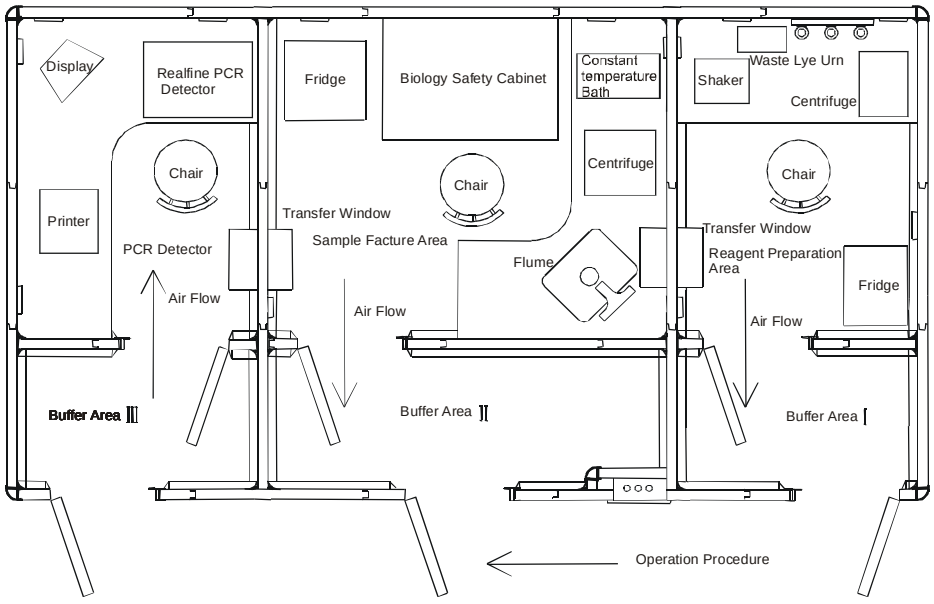
CHAPTER 1 INTRODUCTION

The technique of PCR is advanced in whole life sciences field. However, if we do not understand PCR technique comprehensively or have no relative quality measures, it will lead operator to do test subjectively and stochastically, thus it is possible to get false-positive or false-negative results.

As per characters of PCR technique and the requirements of clinical diagnosis, Ministry of Health P.R.China issued the "Temporary Management Methods of Clinical Gene Lab" in January 2002. The "Methods" made general prescripts of Gene Lab, such as setting, technique checking and accepting, training, surveillance and management, etc. It also requires all of the technicians, who were engaged in clinical PCR, should be trained and licensed before starting to work.

The Clinical Gene Lab is the place where the whole PCR experiment is operated. Whether the settings of Lab are reasonable or not will affect the results of experiment, so the Lab should be set according to "Temporary Management Methods of Clinical Gene Lab" which issued by Ministry of Health P.R.China.

Gene Lab is a Clinical Gene Lab, whose specifications, magnitude, arrangement, position, setting, job specification, operation procedure and management system are definite and argued again and again by several experts. It should also accord with "Temporary Management Methods of Clinical Gene Lab". This Lab adopts Automatic Real-time PCR Detection System, having three workarounds, namely Reagent Preparation Room , Sample Preparation Room and PCR Amplification Room . These three workarounds are arranged ideally in this Lab, and there is a buffer area in the front of each workaround, as showed in Picture 1.



Picture 1. Arrangement of Gene Lab

There are clothes racks and trimness boxes used to change clothes and shoes in the three buffer areas. Each Lab and buffer area has illuminating lamps, UV lamps and ventilators in the top.

In Reagent Preparation Room , there are experimental desk, labets, fridge, mobile UV lamps, transfer window that connects with Sample Preparation Room, and chairs. On experimental desk, there are experimental equipments, including centrifuge, shaker, pipettes, centrifugal tubes, waste lye urn, a waste bin and so on.

In PCR Amplification Room , there are an experimental desk, labets, a transfer window that connects with Sample Preparation Room and a chair. On the experimental desk, there are experimental equipments, including Real-time PCR Detection System, computer, printer, waste lye urn, waste bin and so on.

In suitable place of each area, there are power outlets, telephone outlets, network outlets and air condition pipeline outlets.

CHAPTER 2 CHARACTERS AND SPECIFICATIONS

CHARACTERS

Gene Lab has several obvious characters as following:

1. Ideal arrangement configuration

Adopting Automatic Real-time PCR Detection System in the Gene Lab, we set three workarounds, namely Reagent Preparation Room , Sample Preparation Room, PCR Amplification Room and the corresponding Buffer Area I, Buffer Area II and Buffer Area III. Let's arrange experiment areas and buffer areas as showed in picture 1, so that experimenters could change clothes and shoes in buffer areas before they enter into experiment areas; while reagents and samples could be passed directly through transfer window from Sample Preparation Room to PCR Amplification Room .

2. Standard requirement of air-pressure's setting

In order to avoid reagents and samples being polluted by aerosol and staff and circumstances being polluted by amplification produces during the whole PCR experiment, there is certain differential air-pressure set in every experiment area of Gene Lab. Make sure safety of persons, circumstances and samples, on establishment basis.

3. Precise measures of protection

(1) There is a biology safety labet in Sample Preparation Room, which is used for sample preparation. The ventilation system in the labet can protect people and samples from being polluted by aerosol, thus to ensure safety of people and samples. In biology safety labet, the cleanliness reaches 100 grades.

(2) On the top of each experiment area, buffer area, biology safety labet and transfer window, there is a UV lamp for antisepsis.

(3) In Reagent Preparation Room and Sample Preparation Room, there are mobile UV lamps for local antisepsis of experiment desk.

4. Compendious and clean appearance

SL-6040A Gene Lab is made up of colorized steel plate, aluminum alloy shaped section, glass and so on, and it is supported by aluminum alloy round column; Its inner angles are decorated by inside-radius aluminum alloy, all of these allow the Lab to own firm configuration, classic lines, perfect appearance and excellent leakproofness.

5. Modular design

All of the parts are debugged in the manufactory and assembled in locale conveniently. For this Lab, the capacity is huge, the production is efficient and the quality is credible, so that the cost can be controlled efficiently.

6. Standardization design

Set standard dimensions of Lab to save room, thus to satisfy different customers' requirements.

7. Patent products

This item had gained patent in P.R.China, whose number is: ***ZL 2004 2 0109896.9***

8. Centralized control

All of switches are fixed in a faceplate for centralized control.

9. Humanization design

Some suitable place of experiment desk, transfer window, flume and hydrant in each of experiment area is designed friendly. And in suitable place of each area, there are telephone outlets, network outlets and air condition pipeline outlets.

SPECIFICATIONS

This Lab should comply with the specifications as below.

ITEMS	SPECIFICATIONS	REMARK
Temperature difference between Lab and circumstance	≤3℃	
Total power	≤5kW	
Illumination power	≤600W	
Drive power	≤4400W	
Minimum illumination	≥300lx	
Noises	≤60dB	

REQUIREMENT OF INSTALLATION

Please install the Lab under the following condition.

ITEMS	SPECIFICATIONS	REMARK
Ambient temperature	18～27℃	Can fix air-condition.
Ambient humidity	30%～70%	Can fix humidifier and desiccator.
Supply voltage	AC100-120V /AC220-240V，50-60Hz	
Inlet hydraulic	≥20kPa	
Minimum installation room(m)	6.0X4.5X3.0 (L×W×H)	
Flatness of ground	≤±5mm/2m	

CHAPTER 3 OPERATIONAL PRINCIPLE

principLEs of Gene Lab's setting

1. Gene Lab could be divided into three workarounds:
   (1) Reagent Preparation Room
   (2) Sample Preparation Room
   (3) PCR Amplification Room

As mentioned in Chapter 2, Gene Lab has a special aisle in the front, and the buffer areas of each experiment area are designed in one side of the aisle. These three experiments line in turn as Reagent Preparation Room , Sample Preparation Room and PCR Amplification Room respectively.

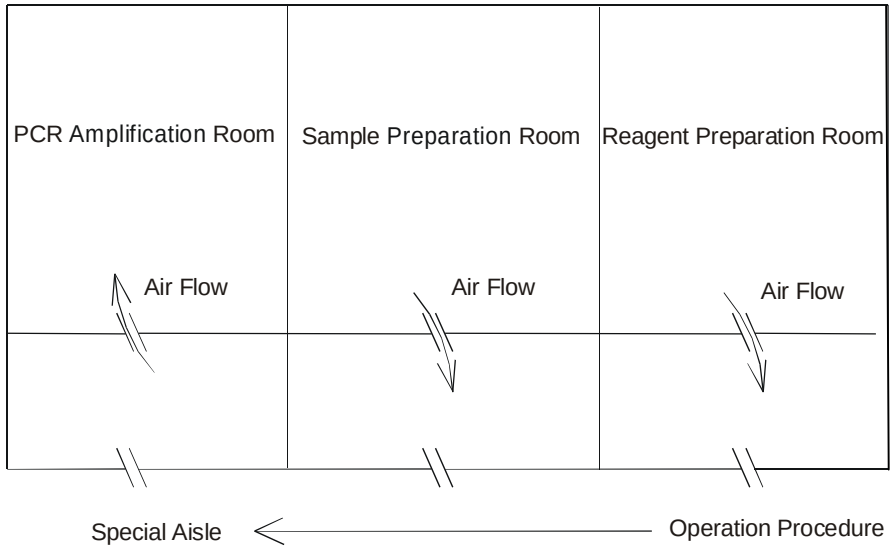
2. Should set a clear sign each for all workarounds so as to avoid mix-using equipments and things among different workarounds.

3. When enter into each workaround, please follow a single direction as: Reagent Preparation Room → Sample Preparation Room → PCR Amplification Room .

4. Should use different work clothes in different workarounds, and should not bring them out when leave.

SETTING OF AIRFLOW'S DIRECTION

In order to avoid the amplification produces being polluted by environment, and to meet the requirements of setting Clinic Gene Lab, the airflow direction should follow the way as below: Reagent Preparation Room to Buffer Area I, Sample Preparation Room to Buffer Area Ⅱ, Buffer Area III to PCR Amplification Room (refer to Picture 2). Therefore, please keep Buffer Area I, Buffer Area Ⅱ and PCR Amplification Room under negative air pressure during operation; While keep other areas' air pressure as "0" or "+". You can turn on the ventilators in Buffer Area I, Buffer Area Ⅱ and PCR Amplification Room to exhaust air. There are controllable air gaps on the outside walls, windows and doors of experiment areas, so as to let fresh air enter indoor.



Picture 2. Ideal arrangement of Gene Lab

COLLOCATION OF EQUIPMENTS IN EACH WORKAROUND (FOR REFERENCE ONLY)

1. Reagent Preparation Room

NO.	EQUIPMENTS	UNIT	QUANTITY
1	Fridge	PCS	1
2	Centrifuge	PCS	1
3	Blending machine	PCS	1
4	Minim- pipette	SUIT	1
5	Mobile UV lamp	PCS	1
6	Special work clothes	SUIT	2
7	Indoor thermometer and hygroscope	PCS	1
8	Fridge thermometer	PCS	2
9	Centrifugal tube	CASE	1
10	Waste lye urn	PCS	1
11	Consumables （such as gloves）	SUIT	2
12	Waste bin	PCS	1
13	Special book and pen for recording	SUIT	2

2. Sample Preparation Room

NO.	EQUIPMENTS	UNIT	QUANTITY
1	High speed centrifuge	PCS	1
2	Blending machine	PCS	1
3	Cooling & Heating Block	PCS	1
4	Biology safety labet	PCS	1
5	Fridge	PCS	1
6	Minim- pipette	SUIT	1
7	Fridge thermometer	PCS	1
8	Mobile UV lamp	PCS	1
9	Indoor thermometer and hygroscope	PCS	1
10	Centrifugal tube	CASE	1
11	Waste lye urn	PCS	1

12	Consumables （such as gloves）	SUIT	2
13	Waste bin	PCS	1
14	Special book and pen for recording	SUIT	2
15	Special working clothes	SUIT	2

3. PCR Amplification Room

NO.	EQUIPMENTS	UNIT	QUANTITY
1	Real-time PCR Detection System	PCS	1
2	Minim- pipette	SUIT	1
3	Mobile UV lamp	PCS	1
4	Indoor thermometer and hygroscope	PCS	1
5	Special working clothes	SUIT	2
6	Computer	PCS	1
7	Printer	PCS	1
8	Waste lye urn	PCS	1
9	Waste bin	PCS	1
10	Consumables（such as gloves）	SUIT	2
11	Special book and pen for recording	SUIT	2

OPERATIONAL PRINCIPLE OF GENE LAB

1. Operational principle of Reagent Preparation Room

Reagent Preparation Room is a place for storing and preparing reagents; what's more, it is the cleanest place in the whole Gene Lab. If reagents are polluted, the PCR experiment produces will be incorrect surely. Hence, air should flow from Reagent Preparation Room to Buffer Area I, to make sure reagents pure in process of storing, preparing and transferring. Besides, should set a UV antisepsis system in Reagent Preparation Room and Buffer Area I for antisepticising environment before start working. After reagents prepared, please divide flow of people and flow of materials, transfer reagents between Reagent Preparation Room and Sample Preparation Room by the transfer window, thus to protect reagents from pollution. Please set a UV antisepsis system in transfer window, and operate transfer window according to standard operation programs.

2. Operational principle of Sample Preparation Room

Sample Preparation Room is a main experiment area in Gene Lab. It includes procedures as below: receiving samples, sorting (DNA, RNA) and storing in low temperature, putting the templates (reverse transcription) into amplification tubes, putting the prepared templates (DNA, RNA) into main reaction mixture, and so on.

As the samples are prepared in the biology safety labet, please control the airflow inside of the biology safety labet to protect operators and samples. The setting of airflow in this area is the same as that of Reagent Preparation Room , and the air should flow from Sample Preparation Room to Buffer Area Ⅱ. There are also UV antisepsis systems in Sample Preparation Room and Buffer Area Ⅱ. After the samples are prepared, they will be transferred to PCR Amplification Room through the transfer window from Sample Preparation Room.

3. Operational principle of PCR Amplification Room

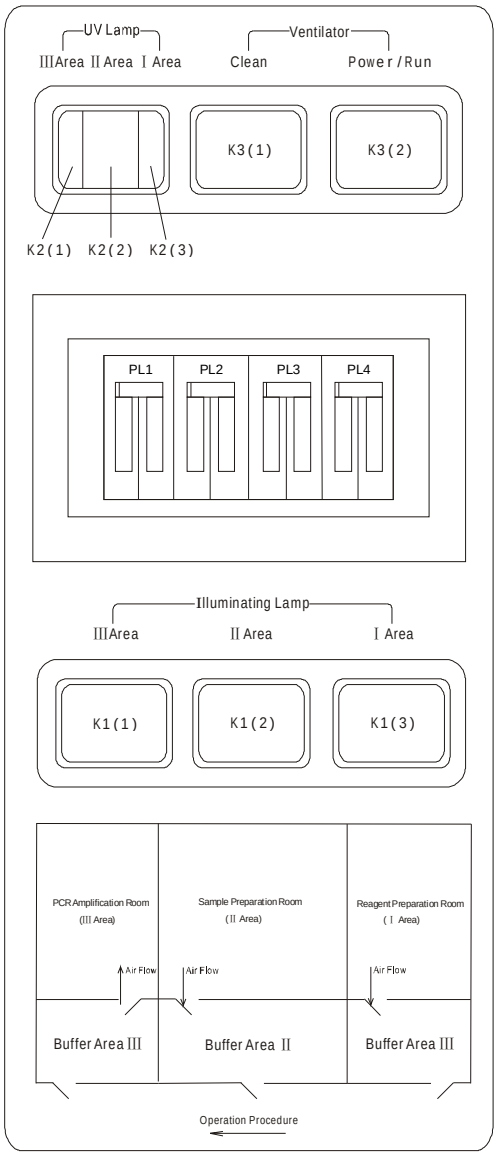
PCR Amplification Room is the area where PCR amplification and amplification produces analysis are carried on. It is the area with most serious pollution in the whole Gene Lab. Hence, please guarantee air flow from Buffer Area III to PCR Amplification Room , and install UV antisepsis systems in PCR Amplification Room and Buffer II Area, thus to avoid pollution to people and environment.

CHATER 4 OPERATION GUIDE

Please enter every area of the Gene lab following the single direction: Reagent Preparation Room →Sample Preparation Room →PCR Amplification Room . The process of the whole operation is listed as below.

ANTISEPSIS

1. Turn on the illuminating lamps K1 (1), K1 (2) and K1 (3) that are shown in picture 3.
2. Move the mobile UV antisepsis lamps to target place (such as experiment desk), then turn on, and then close each door.
3. Turn on the UV antisepsis lamps K2 (1), K2 (2), K2 (3) of area I, area Ⅱ, and area III, and keep the lamps working for more than half an hour. (Refer to " Standard Operation of UV Antisepsis")



Picture 3. Panel of switches

NOTE: People should leave the Lab immediately once UV lamps are turned on to avoid body damage.

WARRING! During UV lamps working, staffs are forbidden to enter Lab.

AIR EXHAUST

Turn off the UV lamps K2 (1), K2 (2), K2 (3) and mobile UV lamps, and then turn the running K3(2) under "Power/Run" and ventilator K3(1) under "Clean" state, keeping all ventilators in each experiment areas and buffer areas exhausting air to outside for ten minutes before starting to operate.

NOTE: Please change work clothes before enter in each experiment area.

PREPARATION OF WORK

Turn off the ventilator K3(1), and keeping K3(2) in "Power/Run" state, thus the ventilators in Buffer I area, Buffer Ⅱ area and PCR Amplification Room start to exhaust air to outside.

NOTE: Do remember to turn off K3 (1) before experimentation.

PREPARATION OF REAGENTS

Staffs should change work clothes in Buffer Area I, while wear gloves and cap in Reagent Preparation Room according to "Work Rules of Reagent Preparation Room ". And then prepare reagents (refer to "The standard operation of Reagent Preparation Room "), put the prepared reagents into transfer window, close the window, turn on the UV lamps in the window (working for 30 minutes in general, refer to "Standard Operation and Maintenance of Transfer Window"), take down the experiment notes in details and clean the experiment desk according to "The Processes to Cleaning Lab". Afterwards, please change work clothes in Buffer Area I, and close the door when leave.

NOTE: Please do not take out the work clothes and castoffs.

PREPARATION OF SAMPLES

Please change work clothes in Buffer Area Ⅱ, while wear gloves and cap in Sample Preparation Room following "Work Rules of Sample Preparation Room". And then turn off the UV lamp in the transfer window, take out the prepared reagents, receive clinical samples, finally, prepare samples in biology safety labet (refer to "Processes of Sample preparation in Sample Preparation Room"), put the prepared samples into another transfer window, transfer them to PCR Amplification Room , close the window, turn on the UV lamp in the window (working for 30 minuets in general, refer to "Standard Operation and Maintenance of Transfer Window"), take down the experiment notes in

details and clean the experiment desk according to "Cleaning Process of Gene Lab". Afterwards, please change work clothes in Buffer Area Ⅱ, and close the door when leave.

NOTE: Please do not take out the work clothes and castoffs.

WARRING! After enter in Sample Preparation Room, remember do not turn back to Reagent Preparation Room.

PCR AMPLIFICATION AND ANALYSIS

Please change work clothes in Buffer Area III; while wear gloves and cap in Sample Preparation Room according to "Work Rules of Sample Preparation Room". Turn off the UV lamp in transfer window, take out the ready-made samples to do PCR amplification and produces analysis Afterwards, take down the experiment notes in details and clean the experiment desk according to "Cleaning Processes of PCR Lab", please change work clothes in Buffer Area III, and close the door when leave.

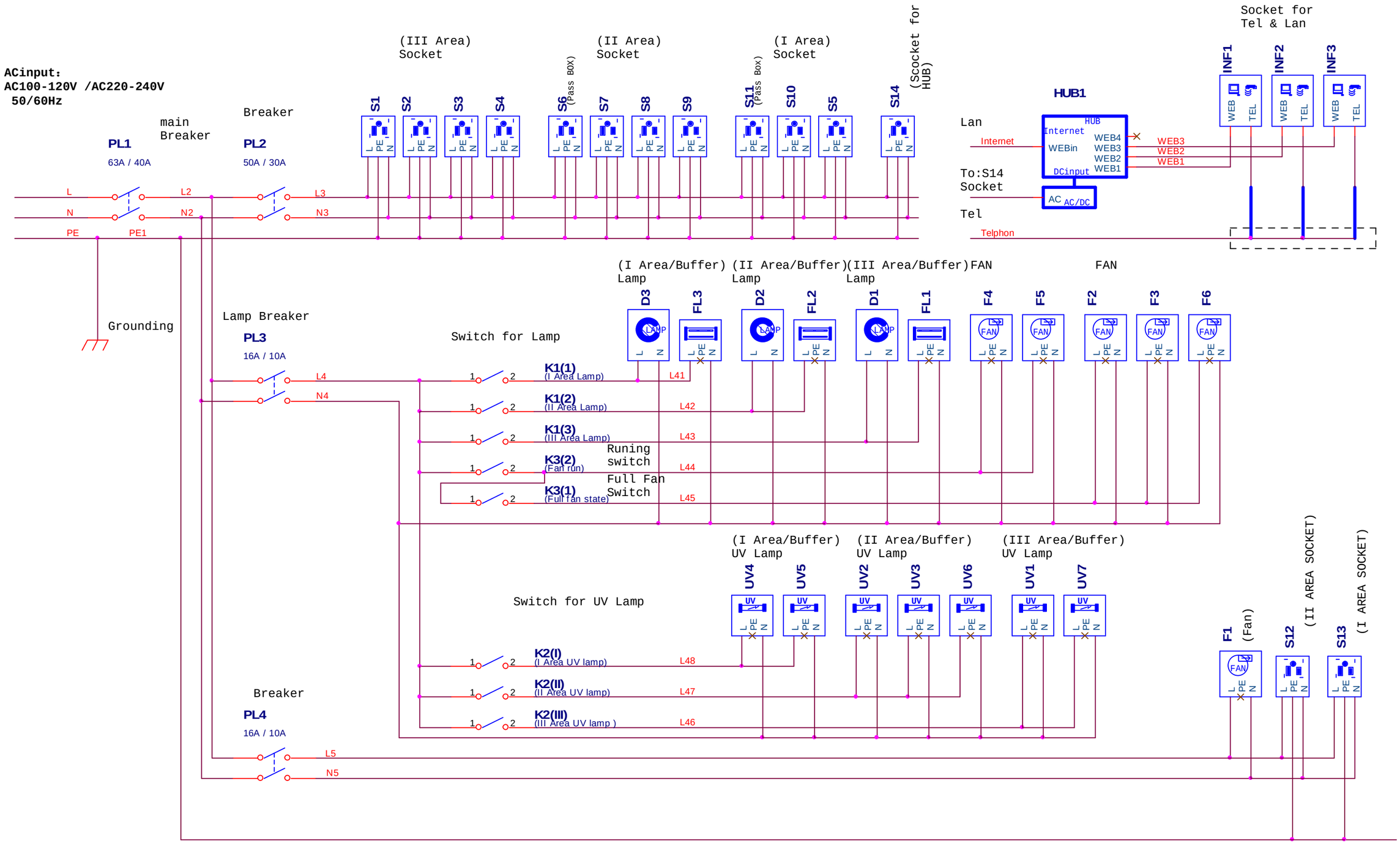
NOTE: Please do not take out the work clothes and castoffs.

WARRING! After enter in Sample Preparation Room, remember do not turn back to Reagent Preparation Room.

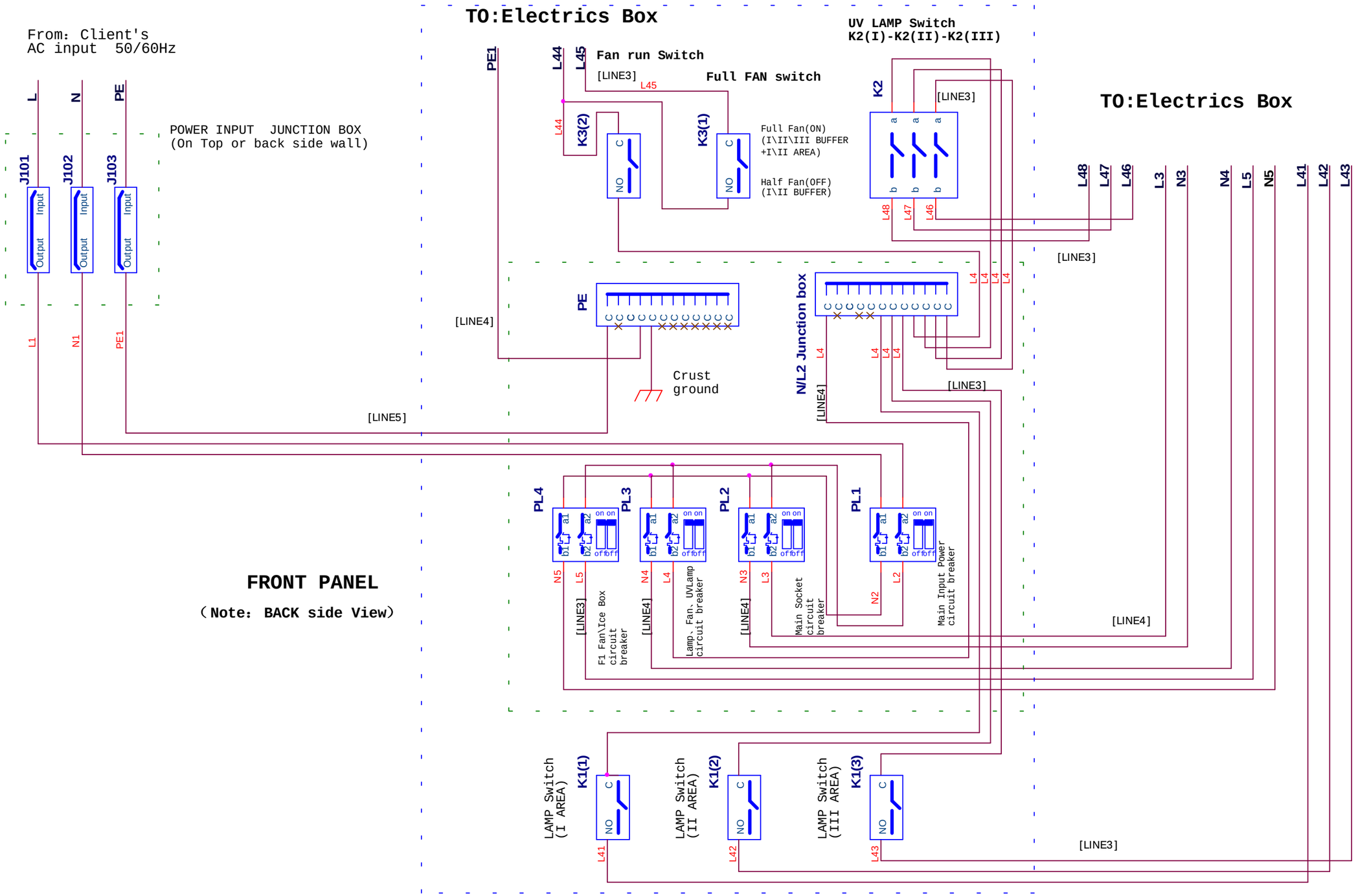
Appendix 1 Troubleshooting and Repair

No.	Trouble	Trouble Analysis	Remedy
1	Some certain Illuminating lamp does not work when press the switches.	Starter is broken.	Change starter.
		Luminous tube is broken.	Change luminous tube.
2	Ventilator in PCR Amplification does not work.	Total power is not connected.	Check the power and connect it.
		PL4 air-switch is not connected.	Check the switch and connect it
		Motor of the ventilator is broken	Change the motor
3	There is no water after turning on the water faucet.	Water faucet's signal wires are unstuck	Firm the signal wires
		Battery is run out.	Change new battery
		Hydraulic pressure is not enough	Enhance hydraulic pressure
4	UV lamp in transfer window does not work.	UV lamp's tube is broken.	Change the UV lamp's tube.
		Power outlet is unstuck.	Firm the outlet.

Appendix 2 Elements Diagram



Appendix 3 WIRING DIAGRAM-1



FRONT PANEL

(Note: BACK side View)

Appendix 4 WIRING DIAGRAM-2